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IMPLEMENTATION OF THE INTERNATIONAL COVENANT ON
ECONOMIC, SOCIAL AND CULTURAL RIGHTS

Substantive issues arising in the implementation of the International Covenant on Economic, Social and Cultural Rights: Day of General Discussion "The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author (article 15.1 (c) of the Covenant)" organized in cooperation with the World Intellectual Property Organization (WIPO)

Monday, 27 November 2000

PROTECTION OF INTELLECTUAL PROPERTY UNDER THE TRIPS AGREEMENT

Background paper submitted by the
Secretariat of the World Trade Organization

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Introduction

1. This paper examines human rights of individuals and public interest as traditional foundations of intellectual property protection and looks at how they are reflected in the present multilateral intellectual property law, in particular in the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), which is part of the Marrakesh Agreement Establishing the World Trade Organizations ("WTO Agreement"). The paper examines the way that the TRIPS Agreement gives effect to the rights envisaged in article 27.2 of the Universal Declaration of Human Rights ("UDHR") and article 15.1 (c) of the International Covenant on Economic, Social and Cultural Rights ("ICESCR"), and gives a number of examples of how the provisions of the Agreement promote certain other human rights. It also studies how the interdependent nature of human rights is mirrored in the emphasis on balance in the TRIPS Agreement, allowing member countries to adopt measures within and outside the IP system to take into account various societal interests in implementing its provisions. The final sections take a closer look at two areas, first the issue of patent protection of pharmaceutical products and its relationship to the promotion of public health, and secondly the current debate on the protection of traditional knowledge and how the TRIPS Agreement relates to that issue.

2. An Annex to the paper contains a brief summary of the main features of the TRIPS Agreement.

Origins and objectives of intellectual property

3. Both human rights and public interest were used to justify early intellectual property systems. The human rights approach was first explicitly manifest in the French revolution. The 1789 Declaration of the Rights of Man and of the Citizen included "property" among the "natural and imprescriptible rights of man". In the context of the adoption of the Law of 1791 providing a right of representation to authors, it was argued that "the property of the work which is born of the writer's thought is the most sacred, the most legitimate, the most unassailable and the most personal of all properties". In the modern context, the notion of a "natural right" might often be replaced by an appeal to a sense of equity and fairness: it is seen as fair that, for example, a free-lance journalist, a composer or an inventor would draw some benefit from others using the fruits of his or her creative efforts for economic gain.

4. The United States Constitution of 1787 justifies the legislative authority granted to the Congress in intellectual property matters on grounds of public interest: "The Congress shall have power [...] to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." The objective of the authority is to promote the progress of science and useful arts; the means to this end is the provision, for limited times, of exclusive rights to authors and inventors.

5. Human rights and the equitable treatment of authors and inventors, on the one hand, and public interest, on the other hand, remain the underpinnings of intellectual property systems. While the civil law tradition might sometimes emphasise more the first and the common law tradition the second approach, it would appear that these two conceptual starting points are complementary rather than mutually exclusive. Besides, it should be noted that the social objectives vary between different areas of IP: while modern copyright and patent laws have

been designed to encourage creative work and technological innovation and provide means to finance research and development, the focus of trade mark laws is more on consumer protection and in ensuring fair competition among traders.

6. The development of national IP systems and international trade during the nineteenth century raised awareness of the need for international protection. After a period of bilateral trade agreements, the first multilateral agreements were concluded, namely the Paris Convention for the Protection of Industrial Property in 1883, and the Berne Convention for the Protection of Literary and Artistic Works in 1886. Since then, these two treaties have been periodically updated and additional treaties have been concluded.

7. The economic importance of intellectual property has grown in recent decades with the increasing role of information and knowledge-based industries. For example, a number of studies showed that by the 1980s the contribution of copyright industries to the gross domestic product of certain countries was in the order of 3-5 per cent. The number of people employed in these industries also grew steadily. With the increasing interdependence of national economies, it became clear that there no longer existed a functioning multilateral rule of law in this area to regulate relations and differences between countries. This led to the inclusion of IP matters in the GATT Uruguay Round negotiations, launched in 1986, and the conclusion of the TRIPS Agreement as part of a package of agreements that make up the WTO. The results were adopted by consensus by the 125 participating Governments. The Agreement entered into force in 1995, although it gives members transitional periods, which differ according to their stage of development, to bring themselves into compliance with its rules. Subject to certain exceptions, developed countries had to implement TRIPS as of the beginning of the year 1996 and developing countries as of the beginning of the year 2000. Least-developed country members may delay application until the year 2006.

IPRs and human rights

8. The TRIPS Agreement is contained in Annex 1C to the WTO Agreement. The overall objectives of the WTO, as reflected in the Preamble to the WTO Agreement, concern also the TRIPS Agreement. The Preamble recognizes that member countries' trade and economic relations "should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development". It also recognizes the "need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development".

9. The objectives of the TRIPS Agreement, as explicitly set out in its article 7, put emphasis on the public interest rationale of intellectual property protection. This article, entitled "Objectives", says that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a

manner conducive to social and economic welfare, and to a balance of rights and obligations". This corresponds with the objectives article 15.1 (a) and 15.1 (b) of the ICESCR, which recognize the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications.

10. While the expressly stated objectives of the WTO Agreement and the TRIPS Agreement lay emphasis on promoting social and economic welfare, articles 27.2 of the UDHR and article 15.1 (c) of the ICESCR underline the need to protect the interests of authors and inventors in the results of their intellectual efforts not only for the sake of the broader public interest but because they are recognized as worthy of protection as such. However, it can be argued that the TRIPS Agreement, including the pre-existing IP conventions incorporated into it,[1] also seeks to give effect at the multilateral level to article 15.1 (c) of the ICESCR, which establishes everyone's "right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author" as a human right.[2] This would appear, for example, to be indicated by the statement in the Preamble to the TRIPS Agreement that recognizes that intellectual property rights are private rights.

11. It should be added that the TRIPS Agreement promotes also other values deemed essential for the realization of human rights. For example, the TRIPS Agreement prohibits discrimination on the basis of the nationality in the area of intellectual property rights;[3] this is supportive of the non-discrimination principles contained in the human rights instruments. The Agreement promotes the rule of law at the national level; it requires, inter alia, the observance of due process by requiring that judicial procedures are fair and equitable, decisions are in writing and reasoned, and that parties have an opportunity to appeal.[4] The Agreement provides for international cooperation to fight copyright piracy and trade mark counterfeiting,[5] which often have links to organized crime.

12. The TRIPS Agreement promotes the rule of law also at the multilateral level between States by commonly agreed rules and peaceful settlement of disputes through a multilateral system. Member countries have agreed to give effect to the minimum standards provided in the Agreement within their own legal system and practice and remain free to implement in their law more extensive protection than required by the Agreement, but it is also made clear in article 1.1 of the Agreement that they are not under any obligation to do so. The Preamble emphasizes the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures. Under the Dispute Settlement Understanding of the WTO ("DSU"), Governments are committed, if they wish to seek redress of a violation of a TRIPS obligation, to have recourse to, and abide by, the multilateral WTO dispute settlement procedures and not to make a determination that a violation has occurred except in accordance with these procedures and not to retaliate except in accordance with authorization from the WTO's Dispute Settlement Body (DSB).[6] The WTO dispute settlement system aims ensure a rule of law in international trade relations through the impartial and effective resolution of disputes between Governments.

Seeking the right balance

13. An objective of intellectual property protection is to promote long term public interest by means of providing exclusive rights to right holders for a limited duration of time.[7] After the

expiration of the term of protection, protected works and inventions fall into the public domain and anyone is free to use them without prior authorization by the right holder. Hence, in the long term there is no conflict but rather a mutually supportive relation between the interests of promoting creativity and innovation and maximizing access. However, during the course of the term of protection, there is potential for conflict between these two considerations, which can also mirror differences between the interests of right holders and users. The challenge of the national and international rule-maker is to find the optimal balance between various competing interests with a view to maximizing the public good, while meeting also the human rights of authors and inventors. Article 7 of the TRIPS Agreement emphasizes the need for balance: "the mutual advantage of producers and users of technological knowledge" and "a balance of rights and obligations". The tensions inherent between subparagraphs (a) and (b), on the one hand, and subparagraph (c) of article 15.1 of the ICESCR, on the other hand, are those that underlie also the considerations of balance in IP systems.[8]

14. An optimal balance within IP systems at the national or multilateral level can be reached by properly determining the definition of protectable subject matter, scope of rights, permissible limitations and term of protection. This balance is constantly developing both at the national and international level in response to economic and technological as well as political developments. The TRIPS Agreement is a minimum rights agreement that leaves a fair amount of leeway to member countries to implement its provisions within their own legal system and practice and fine-tune the balance in the light of domestic public policy considerations.[9] Below are a few remarks about the role of these four elements in determining the scope of IP protection.

15. An important part of the balance is a careful definition of protectable subject matter. For example, copyright protection does not cover any information or ideas contained in a work; it only protects the original way that such information or ideas have been expressed in a work.[10] As regards patents, the starting-point in the TRIPS Agreement is that for an invention to be patentable it must be new, involve an inventive step and be capable of industrial application.[11] For example, biological material in its natural state is not patentable. Furthermore, the Agreement recognizes the importance of ethical and other considerations by allowing a country, even where an invention meets the normal rules for patentability, to refuse to grant a patent if the commercial exploitation of the invention is prohibited on grounds of public order or morality, including if its exploitation might be dangerous to life or health or seriously prejudicial to the environment.[12] Diagnostic, therapeutic and surgical methods for the treatment of humans or animals may be excluded from patentability. In addition, the TRIPS Agreement provides for some special flexibility in the area of biotechnology, allowing members to refuse patents for plant and animal inventions (other than micro-organisms and microbiological processes). One condition is that, if patents are not available for new plant varieties, an alternative so-called "effective sui generis" system must be provided.[13] This provision of the TRIPS Agreement is presently being reviewed by the TRIPS Council.[14]

16. The Agreement does not define further the conditions for patentability, thus leaving member countries considerable discretion in this regard. A higher threshold for patentability limits the scope for patenting, but makes it more difficult for innovators to utilize the system, perhaps especially in developing countries. In regard to this threshold, a distinction should be made between the minimum requirements under the TRIPS Agreement and the practices of some member countries, which may go beyond what is required by the Agreement.

17. In the bioethics debate it is important not to confuse three distinct issues that may arise in relation to new technology. Of them, only the third one, relating to patentability, is an intellectual property issue, and Governments' freedom to act on the first two is not limited by obligations under the TRIPS Agreement:

- whether and, if so, subject to what conditions research into biotechnology should be allowed to take place;

- whether and, if so, subject to what conditions the results of research into biotechnology should be allowed to be exploited, for example through the commercialization of bioengineered crops;

- whether the inventor of a biotechnological invention should have the right to prevent other people from using his invention for a limited period of time.

18. A more general point that should be made is that the grant of an IP right does not impair the possibility for Governments to regulate production and the use and distribution of products on any public policy grounds, such as concerns about public order, morality, health or environment.[15] This is because a patent and other intellectual property right do not guarantee the right of the right holder to use the invention or other protected subject matter; they are only concerned with the right of the right holder to prevent others from doing so.

19. A key feature in achieving a proper balance in IP regimes is granting protection only for a limited period, which should be appropriately long to provide the necessary incentive and reward for creative work and innovation. After the expiration of the term of protection, the work or invention falls into the public domain, and everyone is free to use it without restriction. The fact that IP systems provide for a limited period of protection is an indication that in all such systems the protection of the rights of authors and inventors are not absolute but are balanced by considerations of public interest.[16]

20. The TRIPS Agreement provides a fair amount of leeway to member countries to adjust the level of protection by providing limitations and exceptions to exclusive rights. The Agreement contains general clauses that permit limitations and exceptions to exclusive rights, provided that they address specific situations, do not conflict with a normal exploitation of the protected material and do not unreasonably prejudice the legitimate interests of right holders.[17] In addition, the Agreement and the Conventions incorporated in it allow for numerous specific limitations and contain provisions on compulsory licences.

21. One of the basic objectives of the patent system is to facilitate the dissemination of technological knowledge by encouraging inventors to disclose new technology rather than attempt to keep it secret. Article 29.1 of the Agreement requires that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by others. The resulting information, which is stored and classified in patent documentation, is accessible to anyone, including to those in countries where a patent has not been sought. One of the purposes of this disclosure requirement together with the research or

experimental use exception that is typically found in national patent laws is to ensure that the technological and scientific knowledge contained in a patented invention can be used for further research already during the patent term.[18]

22. As noted above, copyright protection does not cover any information or ideas contained in a work; it only protects the original way that such information or ideas have been expressed in a work. Thus everyone is free to use the information contained in a work. In addition, the TRIPS Agreement and national copyright laws contain numerous specific limitations that allow free use of a work, including in regard, inter alia, to circulation of news and education.[19] An Appendix to the Berne Convention, also incorporated into the TRIPS Agreement, allows developing countries, under certain conditions, to grant compulsory licences for educational purposes.

23. The preoccupation in the TRIPS Agreement with balance is also reflected in the provisions concerning enforcement of intellectual property rights. While the Agreement requires that enforcement procedures must be such as to permit effective action, it also requires that they must be applied in a manner that avoids the creation of barriers to legitimate trade and safeguards against their abuse must be provided. Such procedures must be fair and equitable.[20]

24. An important part of IP policy is that Governments take appropriate measures in other areas of economic and social policy that enable the society to benefit from the IP system and to prevent its abuse. Article 8 of the TRIPS Agreement, entitled "Principles", recognizes that "members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement". It adds that "[a]ppropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology".[21]

25. Finding the right balance at the national level is often difficult. Agreeing a suitable framework for protection at the international level between countries with different political and economic systems and different levels of development is even harder. However, during the GATT Uruguay Round negotiations there was a widely held view that common rules with multilateral dispute resolution were preferable to a proliferation of bilateral disputes. These were negotiations in which all the sometimes conflicting public policy considerations that underlie the IP system entered into play. One of the ground rules agreed for the negotiations was that consideration would be given to the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.[22] In the negotiations compromises were made by negotiators on all sides.[23]

26. Rights under article 27.2 of the UDHR and article 15.1 (c) of the ICESCR together with other human rights will be best served, taking into account their interdependent nature, by reaching an optimal balance within the IP system and by other related policy responses. Human rights can be used - and have been and are currently being used - to argue in favour of balancing

the system either upwards or downwards by means of adjusting the existing rights or by creating new rights. Which way serves the best the objectives of human rights is at the end a matter of social and economic analysis and empirical evidence.

Patent protection for pharmaceutical products

27. The issue of patent protection for pharmaceutical products is one where the problem of finding a proper balance is particularly acute. On the one hand, it is especially important from a social and public health point of view that new drugs and vaccines to treat and prevent diseases are generated and the incentives provided by the patent system are particularly important in this regard. On the other hand, precisely because of the social value of the drugs so generated, there is strong pressure for such drugs to be as accessible as possible as quickly as possible.

28. The TRIPS Agreement represents an effort to find an appropriate balance between these considerations. On the one hand, the Agreement requires that, after the end of the relevant transition period, patent protection for pharmaceutical products should be available for a 20-year term of protection. On the other hand, the Agreement contains a substantial number of provisions which enable Governments to implement their intellectual property regimes in a manner which takes account of immediate as well as longer term public health considerations. These provisions, some of which have already been mentioned, include those relating to certain exemptions from patentability, the possibility to make limited exceptions to exclusive rights,[24] compulsory licensing, parallel importation and the recognition that member countries may adopt measures necessary to protect public health and nutrition (for example, many countries have price or reimbursement controls, generic substitution policies, etc.). These various provisions were the result of several years of hard negotiation and involved important concessions on the part of the major demandeurs for the TRIPS negotiations. They recognize and legitimize in public international law the right of countries to qualify patent rights in certain ways.

29. It is important to put the impact of the TRIPS Agreement on access to drugs in developing countries into perspective:

- Most developing countries have provided product patent protection for pharmaceuticals all along or have introduced it prior to the end of the transition period to which they are entitled under the TRIPS Agreement (2005 for developing countries and 2006 for least developed countries[25]). Only a handful of WTO members are using the full transition period.

- Most drugs, including most of those vital for essential health care in developing countries, are not under patent protection anywhere and are in the public domain.[26]

- In many of the poorest countries, for example in Sub-Saharan Africa, patents have not been sought and granted for drugs even where they are patentable under their national laws.

- The effective period of patent protection for pharmaceuticals that use new chemical entities is very much shorter than the nominal 20-year period, especially in developing countries, because of the time taken to obtain marketing approval from the public health authorities.

30. It should also be noted that the TRIPS Agreement does not stand in the way of prices for patented pharmaceuticals being modulated to take into account the capacity to pay of different countries and the populations within them. The WTO Secretariat is examining the issue of differential pricing in the context of its cooperation with the World Health Organization. The two Secretariats are jointly preparing a workshop of interested parties which would seek to examine the legal, institutional and political environment that would favour widespread use of differential pricing.

31. For the private sector to make a significant contribution to developing vaccines and drugs to treat the neglected diseases of the poor, patent protection is necessary. However, it is recognized that patent protection may not be sufficient in many cases where the purchasing power of those afflicted is low. Especially now that developing countries have committed themselves through the TRIPS Agreement to share some of the burden of providing incentives for research and development, it is more than ever important that, where necessary, the patent system is complemented with other forms of support from the international community for research and development into neglected diseases.

32. It should also be recalled that there is a strong relationship between trade, poverty and health. While improved health is good for development, development and the increased resources that it provides are vital for promoting public health. And the open trading system which the GATT/WTO has sought to establish, of which the TRIPS Agreement is an integral part, is vital for creating opportunities for development.

Traditional knowledge

33. The issue of protection of traditional knowledge is currently being discussed by the international community, including the TRIPS Council. One of the concerns that has been expressed relates to the patenting by foreigners of traditional knowledge. Under the principles contained in the TRIPS Agreement, this should not be possible. For something to be patentable under the TRIPS Agreement, it has to be an invention which includes meeting tests of novelty and inventive step, that is to say it must not be part of what patent officials refer to as "the prior art". Traditional knowledge clearly would not meet these tests. There have been cases where, improperly, patents have been granted for knowledge which turns out not to be new, but traditional. In such cases, patents can be, and have been, invalidated.

34. One of the practical problems that gives rise to such improper grants of patents is that much traditional knowledge is not recorded in databases that can be consulted by patent examiners when they decide whether to grant a patent. Efforts are being made, both at the national level and at the international level to remedy this problem by drawing up appropriate databases. One organization working on this is the World Intellectual Property Organization ("WIPO").

35. Another concern that has been raised, especially about indigenous peoples' traditional knowledge, is that the intellectual property system does not provide sufficient opportunities for the communities where the knowledge originated to protect it from use by others. This type of concern has also been expressed about other traditional cultural manifestations, such as folklore.

36. Of course, to some extent the existing intellectual property system can help in this regard, through its various fields, including the rights of authors and performers, trade marks, including certification marks, geographical indications, industrial designs, patents and trade secrets. This applies perhaps particularly with collective rights, such as geographical indications and collective and certification marks, but individual rights may also be of use.

37. Debate has begun as to whether the existing intellectual property system should be complemented with forms of protection more specifically directed to traditional knowledge, especially of indigenous and local communities. The study of these matters is underway in WIPO and proposals for action have been made also in the WTO. It is recognized that this issue gives rise to complex and difficult questions. For example, while some intellectual property rights are potentially indefinite in duration, such as trade marks and geographical indications, a key feature of the balance in the main intellectual property rights relating to creations and inventions is that, after a temporary period of protection, such creations or inventions fall into the public domain and become freely usable by mankind at large.

38. A related topic is IP and biodiversity, in particular the relationship between the TRIPS Agreement and provisions on these matters of the Convention on Biological Diversity ("CBD"). The TRIPS Agreement, which deals with intellectual property, is silent on the issues addressed in the CBD of the rights of countries to regulate access to biological resources in their territories on the basis of the principle of prior informed consent and of arrangements for benefit-sharing. This silence means that the TRIPS Agreement leaves Governments free to legislate in accordance with the requirements of the CBD on these matters.

Notes

[1] The TRIPS Agreement sets out the minimum standards of protection to be provided by each member by requiring, first, that the substantive obligations of the main conventions of the WIPO, the Paris Convention and the Berne Convention, must be complied with, and, secondly, by adding rules on certain matters where the pre-existing conventions are silent or were seen as being inadequate. Authors' moral rights conferred under article 6 bis of the Berne Convention were not incorporated into the TRIPS Agreement as not being trade-related. However, this does not affect the obligations of WTO members that are also parties to the Berne Convention to protect moral rights.

[2] These articles are closely inter-linked with the provisions of article 17 of the UDHR that provide that "[e]veryone has the right to own property alone as well as in association with others" and that "[n]o one shall be arbitrarily deprived of his property".

[3] See articles 3-5 of the TRIPS Agreement.

[4] See Part III of the TRIPS Agreement.

[5] See article 69 of the TRIPS Agreement.

[6] See article 23 of the DSU.

[7] For the sake of simplicity, the discussion in this Section is limited to copyright and patents. It should be noted that the social objectives and the means of accomplishing them are somewhat different as regards the protection of distinctive signs, such as trade marks and geographical indications.

[8] National and international IP laws also contain provisions that take into account the need to pursue policies that promote also other rights envisaged in the human rights instruments, such as the freedom of expression.

[9] See article 1.1 of the TRIPS Agreement.

[10] See article 9.2 of the TRIPS Agreement.

[11] See article 27.1 of the TRIPS Agreement.

[12] See article 27.2 of the TRIPS Agreement.

[13] Such a system offers greater flexibility than a patent. For example, countries which have such plant variety protection frequently allow so-called "farmers' privilege" by which farmers can resow on their own land protected varieties they have grown without having to buy new seed each year and a breeders' exemption, which ensures that, as a rule, protected plant varieties can be freely used for further breeding practices.

[14] See article 27.3 of the Agreement.

[15] This is explicitly stated in article 17 of the Berne Convention, which is incorporated into the TRIPS Agreement.

[16] However, it might be noted that in the discussion on traditional knowledge a concern is sometimes expressed about the time-limited nature of intellectual property rights.

[17] See articles 13, 17, 26.2 and 30. There are some differences between the wording of these articles.

[18] The scope of the experimental or research use exception provided for in article 30, dealing with patents, was the subject of a recent WTO panel report (Canada - Patent Protection for Pharmaceutical Products). The Panel decided that article 30 covered a provision of Canadian law which permits the use by generic producers of patented products, without authorization and prior to the expiry of the patent term, for the purposes of seeking regulatory approval from public health authorities for the marketing of their generic version as soon as the patent expires (sometimes referred to as the "regulatory exception" or as a "Bolar" provision). See document WT/DS114/R.

[19] Such exceptions are contained in the provisions of the Berne Convention that have been incorporated into the TRIPS Agreement. They include reproduction in certain special cases (art. 9 (2)), quotations and use of works by way of illustration for teaching purposes (art. 10), reproduction of newspaper or similar articles and use of works for the purpose of reporting current events (art. 10 bis), and ephemeral recordings (art. 11 bis (3)).

[20] See article 41 of the TRIPS Agreement.

[21] In addition, article 40 of the TRIPS Agreement recognizes that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology. Member countries may adopt, consistently with other provisions of the Agreement, appropriate measures to prevent or control practices in the licensing of intellectual property rights which are abusive and anti-competitive. The article provides for a mechanism whereby a country seeking to take action against such practices involving the companies of another member country can enter into consultations with that other member to seek its cooperation through the supply of information of relevance to the matter in question.

[22] This was decided in the mid-term review of the Uruguay Round negotiations, completed in April 1989, and is reflected in the fifth recital of the Preamble to the Agreement.

[23] For example, a short list of the main areas in which some major demandeurs made important compromises in the patent and related areas alone would include the rules on the patentability of plants and animal inventions, compulsory licensing, exhaustion and parallel importation, transitional periods and test data protection.

[24] As mentioned above, a recent WTO panel referred to above (WT/DS114/R) upheld the consistency with this provision of the "regulatory exception" in Canadian patent law, which enables generic pharmaceutical producers to use a patented drug without authorization from the patent owner and during the term of the patent for the purposes of obtaining regulatory approval for their generic version. If such an exception to patent rights was not permissible, the arrival on the market of generic competitors would be delayed by some years.

[25] See articles 65.2, 65.4 and 66.1.

[26] The fact that these drugs and other interventions are far from fully exploited in many developing countries indicates that national and international efforts to improve financing, distribution and healthcare infrastructure are vital.

ANNEX

The Main Features of the TRIPS Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") is contained in Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (the "WTO Agreement") of 15 April 1994, which entered into force on 1 January 1995. The Agreement aims to ensure the adequate protection and effective enforcement of intellectual property rights and the impartial resolution of disputes between WTO members about such matters, to the mutual advantage of both producers and users of intellectual property.

The areas of intellectual property that the TRIPS Agreement covers are: copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations); trade marks including service marks; geographical indications; industrial designs; patents, including the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information, including trade secrets and test data.

In respect of each of these areas of intellectual property, the Agreement sets out the minimum standards of protection to be provided by each member. Each of the main elements of protection is defined, namely the subject matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. The standards build on those in the main pre-existing WIPO Conventions, substantive provisions of which are incorporated into the Agreement by reference.

The second main set of provisions in the Agreement lays down requirements for national procedures and remedies for the enforcement of these intellectual property rights (IPRs): general principles applicable to all IPR enforcement procedures; civil and administrative procedures and remedies; provisional measures; special border enforcement measures; and criminal procedures. These procedures and remedies must enable right holders to enforce their rights effectively and also provide for safeguards against the abuse of such procedures and remedies as barriers to legitimate trade.

The Agreement makes disputes between WTO members about the respect of TRIPS obligations subject to the WTO's integrated dispute settlement procedures.

In addition, the Agreement provides for certain basic principles, such as national and most-favoured-nation treatment, and some general rules to ensure that procedural difficulties in acquiring or maintaining IPRs do not nullify the substantive benefits that should flow from the Agreement.

The TRIPS Agreement is an integral part of the WTO Agreement, and it is binding on each member of the WTO from the date the WTO Agreement becomes effective for it. However, the TRIPS Agreement gives members transitional periods, which differ according to

their stage of development, to bring themselves into compliance with its rules. Subject to certain exceptions, developing countries had to implement TRIPS as of the beginning of the year 2000. Least-developed country members may delay the application until the year 2006.

The Agreement is administered by the Council for TRIPS, open to all members, which reports to the WTO General Council.

Further information on the TRIPS Agreement and the work of the TRIPS Council can be found on the WTO Web site at http://www.wto.org (go to the "A-Z list" and click on "Intellectual property").